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Biologicals

journal homepage: www.elsevier.com/locate/biologicals

Biotechnological products in Pan American Health Organization (PAHO): Regional efforts towards harmonization of regulation

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In order to be better informed regarding regulations in place in the Region for biological and biotechnological products, a review of the regulation of biological and biotechnological products in Latin American and Caribbean countries was conducted by the Pan American Health Organization (PAHO) and published in *Biologicals* in 2009 [1]. Results indicated that most of the countries surveyed in 2008 had regulations in place for biological products. Some countries had licensed therapeutic biological medicines as “biosimilars” but information about the pathways used to grant a license under this category was not surveyed.

Countries in the Americas have shown a great interest in having harmonized documents for licensing biotechnological products. Efforts to harmonize regulations among Member States include the work of the Pan American Network on Drug Regulatory Harmonization (PANDRH). PANDRH is formed by all Member States of the Americas. This network is an initiative of all the National Regulatory Authorities (NRA's) in the Region and PAHO. It currently supports the processes of pharmaceutical regulatory harmonization in the Americas within the framework of national and sub-regional health policies and recognizing pre-existing asymmetries. The main components of PANDRH are: the Pan American Conference, the Steering Committee, Technical working groups in priority areas and the PAHO [2].

In January 2010, the Steering Committee of PANDRH approved the establishment of a technical working group on biotechnological products (BIO WG). The mission of the BIO WG is to promote the development of the regulation of biotechnological products in the countries of the Americas region, and to generate more effective and harmonized mechanisms for the regulation of this category of medicines. The members of this group are the NRA's of Argentina, Barbados, Brazil, Canada, Chile, Cuba, Guatemala, Panama, Peru, Trinidad & Tobago and Venezuela, pharmaceutical industries represented by FIFARMA and ALIFAR, and PAHO which acts as Secretariat. The country coordinator of this group is Brazil.

The main objectives of the BIO WG are to:

1. Compile a list of all regulations related to biotechnological products in place at country level and make them available at the regional level, including those for similar biological products where available.

2. Establish a glossary of terms to help understand the situation in Member States and to facilitate further development of related documents.
3. Promote the exchange of information among National Regulatory Authorities of the Region.
4. Identify regional documents and guidelines for development in the short and medium term and elaborate on them as appropriate.
5. Identify other issues related to the regulation of biotechnological products that may require special treatment and establish working plans to address them.
6. Develop tools and training programs to strengthen capacity building among the National Regulatory Authorities of Member States in relation to the regulatory oversight of biotechnological products and related matters.

World Health Organization guidance and general developed documents on biological products are well known and currently used by countries in the PAHO Region for the establishment of local regulations. Therefore, translation into Spanish and Portuguese of the WHO Guidelines on evaluation of similar biotherapeutic products (SBPs) [3] and acquiring copyright permission for its later publication was part of the working plan of the BIO WG, and it is already available [4].

Conflict of interest

Author has disclosed no potential conflicts of interests.

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